PATENT
Docket No. 293.00010102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants:	Daryll A. EMERY et al.	Group Art Unit:	1655
Serial No.:	10/749,602	Examiner:	Patricia A. Leith
Confirmation No.:	8548		
Filed:	December 31, 2003		
For:	IN OVO DELIVERY OF AN IMMUNOGEN CONTAINING IMPLANT		

REPLY BRIEF

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Sir:

This Reply Brief is presented in support of the Appeal filed October 15, 2009 and supplements the Appeal Brief filed December 15, 2009. This Reply Brief is filed in reply to the Examiner's Answer issued March 16, 2010.

This Brief is being submitted as set forth in 37 C.F.R. §41.41(a)(1) and 37 C.F.R. §41.43(b). Please charge Deposit Account No. 13-4895 the fee for filing this Brief under 37 C.F.R. §41.20(b)(2).

I. STATUS OF CLAIMS

Claims 34-44, 67-69, 71-82, and 84-102 are pending and are the subject of this Appeal (see Claim Appendix).

Claims 34-44, 67-69, 71-82, and 84-102 stand rejected.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 34, 37, 39-43, 67-69, 84-86, 89, 91-95, and 97-102 are patentable under 35 U.S.C. §103(a) over Emery et al. (U.S. Patent No. 5,538,733), in view of Emery et al. (U.S. Patent No. 5,830,479) in view of Phelps et al. (U.S. Patent No. 5,339,766).

The Final Rejection further identifies claim 83 as rejected under 35 U.S.C. §103(a) over Emery et al. (U.S. Patent No. 5,538,733), in view of Emery et al. (U.S. Patent No. 5,830,479) in view of Phelps et al. (U.S. Patent No. 5,339,766). However, claim 83 was canceled in Appellants' response filed May 15, 2007 and is, therefore, not subject to the instant Appeal.

Whether claims 34-44, 67-69, 71-82 and 84-102 are patentable under 35 U.S.C. §103(a) over Emery et al. (U.S. Patent No. 5,830,479) in view of Phelps et al. (U.S. Patent No. 5,339,766) in view of Emery et al. (U.S. Patent No. 5,538,733), and further in view of Evans et al. (U.S. Patent No. 6,500,438).

III. ARGUMENT

Claims 34, 37, 39-43, 67-69, 84-86, 89, 91-95, and 97-102 are patentable under 35 U.S.C. §103(a) over Emery et al. (U.S. Patent No. 5,538,733), in view of Emery et al. (U.S. Patent No. 5,830,479) in view of Phelps et al. (U.S. Patent No. 5,339,766).

Claims 34-44, 67-69, 71-82 and 84-102 are patentable under 35 U.S.C. §103(a) over Emery et al. (U.S. Patent No. 5,830,479) in view of Phelps et al. (U.S. Patent No. 5,339,766) in view of Emery et al. (U.S. Patent No. 5,538,733), and further in view of Evans et al. (U.S. Patent No. 6,500,438).

Appellants respectfully submit that the Examiner has erred in maintaining the rejections that are the subject of this Appeal for at least all of the reasons set forth in the Appeal Brief filed December 15. 2009. This Reply Brief is submitted to address errors in the Examiner's Answer issued March 16, 2010.

The Examiner errs by failing to appreciate the different immunological environments experienced by an unhatched poult compared to the immunological environment experienced by a newly hatched poult, particularly with regard to vaccinating eggs that contain maternal antibodies that are directed against an immunogen in the vaccine. Throughout the Examiner's Answer, the Examiner provides no art-recognized rebuttal to Appellants' positions, but instead expresses "opinion of the Examiner" based on an incomplete understanding of an incomplete selection of the prior art.

Each of claims 34, 69, and 84 is independent. Each independent claim recites, in part, administering a vaccine that includes an SRP immunogen to an egg (or a population of eggs) that possesses maternal antibody to the SRP immunogen. Appellants explained in the Appeal Brief one important reason that one of ordinary skill in the art could not have predicted that such vaccination would produce an adaptive immune response in the poults after hatching:

> Immune tolerance to a foreign antigen can occur when a subject is exposed to a foreign antigen under conditions that elicit specific unresponsiveness to the foreign antigen rather than an adaptive humoral immune response to the antigen. In other words, under some circumstances, exposure to a foreign antigen does not

> necessarily result in the challenged subject mounting an adaptive immune response, but instead results in the subject's immune system perceiving the foreign antigen as "self" and establishing antigen-specific immune non-response. (Appeal Brief, page 10, emphasis in original).

Thus, not only would one of ordinary skill in the art be unable to predict whether an adaptive immune response could be successfully induced by vaccinating *in ovo* in the presence of maternal antibodies to the SRP immunogen, the skilled person would further have specific reason to believe that such vaccination would induce exactly the opposite of the desired effect—i.e., immune tolerance to the immunogens in the vaccine.

The Examiner errs by incorrectly interpreting the cited prior art, failing to appreciate the differences between the claimed subject matter and the state of the cited prior art, and incorrectly applying the cited prior art to the claimed subject matter. The following paragraph illustrates the many errors in the Examiner's positions.

> Appellants' assertions are unsubstantiated and found unpersuasive to the Examiner in view of the prior art teachings. Emery '733 explicitly taught *in-ovo* [sic] vaccination using sustained/delayed release of SRP antigen to vaccinate poultry. Although there is no specific example of where Emery performed *in-ovo* [sic] vaccination; [sic] there is an explicit suggestion for the ordinary artisan to perform *in-ovo* [sic] vaccination by Emery et al. and further, *in-ovo* [sic] vaccination techniques were well-known and conventional in the art at the time the invention was made. While Appellants point to unknown parameters and unpredictability with regard to *in-ovo* [sic] vaccination, it is the opinion of the Examiner that the level of unpredictability in the Instant [sic] case does not rise to the level of patentability (of the claimed invention) considering that the prior art explicitly suggested *in-ovo* [sic] vaccination of birds, specifically taught the delayed/sustained release times of the claims and specifically taught the use of SRP proteins for these purposes. (Examiner's Answer, page 17).

Each of Appellants' independent claims recites administering a vaccine that includes an SRP immunogen to an egg (or a population of eggs) that possesses maternal antibody to the SRP immunogen. The Examiner's errors are itemized below.

"Emery '733 explicitly taught *in-ovo* [sic] vaccination using sustained/delayed release of SRP antigen to vaccinate poultry."

This is incorrect, Emery '733 teaches vaccination of one-day-old animals, not eggs. Emery '733 simply does not teach what the Examiner asserts is "explicitly" taught by the document. The Examiner acknowledges as much in the next sentence, stating, "there is no specific example of where Emery performed *in-ovo* [sic] vaccination[.]"

"...there is an explicit suggestion for the ordinary artisan to perform *in-ovo* [sic] vaccination by Emery et al."

As stated above, this comment cannot be based on the teaching of the Emery '733 patent since the disclosure of Emery '733 is limited to the vaccination of day old animals. Appellants therefore suspect that the Examiner is drawing the asserted suggestion from Emery '479.

The comment displays the Examiner's incomplete understanding of the claimed subject matter and/or the Examiner's incorrect application of the prior art to the claimed subject matter. Emery '479 teaches that SRPs may be administered *in ovo*, but Emery '479 describes doing so, in contrast with Emery '733, in the absence of maternal antibodies to SRPs. One skilled in the art, however, would not simply predict that the teaching of *in ovo* delivery of SRPs in the absence of maternal antibodies to SRPs could be extrapolated to *in ovo* delivery of SRPs to eggs that contain maternal antibodies to SRPs and, similarly, one skilled in the art would not extrapolate the administration of SRPs in the presence of maternal antibodies against SRPs from post-hatch to *in ovo* administration because of additional knowledge possessed by one skilled in the art regarding the induction of possibility of inducing immune tolerance by doing so.

When the skilled person fully considers the risks of vaccinating eggs that contain maternal antibodies to an immunogen present in the vaccine, the combination of Emery '733 and Emery '479—an incomplete selection of the art known to a skilled person at the time the

invention was made—fails to provide the explicit suggestion to vaccinate eggs that contain maternal antibodies to an immunogen of the vaccine.

"...*in-ovo* [sic] vaccination techniques were well-known and conventional in the art at the time the invention was made."

The relevance of this statement in the context of the patentability of Appellants' claims is unclear. Appellants do not dispute that it was technically feasible to administer vaccinations *in ovo*. Indeed, Appellants do not and have not ever relied on any particular method of delivering the SRP immunogens *in ovo* in support of patentability of the claims. Instead, Appellants rely on the unpredictability of the result of vaccinating eggs that contain maternal antibodies to an immunogen of the vaccine.

"While Appellants point to unknown parameters and unpredictability with regard to *in-ovo* [sic] vaccination,..."

The Examiner again demonstrates an incomplete understanding of Appellants' remarks and the claimed subject matter. Appellants do not, as asserted by the Examiner, point to unpredictability with regard, generally, to *in ovo* vaccination. Rather, Appellants point to unpredictability with regard to the specific circumstances of vaccinating *in ovo* in the presence of maternal antibodies to an immunogen of the vaccine.

"...considering that the prior art explicitly suggested *in-ovo* [sic] vaccination of birds, specifically taught the delayed/sustained release times of the claims and specifically taught use of SRP proteins for these purposes."

The actual prior art explicit teachings are:

1) *in ovo* vaccination of birds in the absence of maternal antibody to any immunogen in the vaccine (Emery '479);

2) vaccination of one-day-old poults using delayed/sustained release, in some cases in the presence of maternal antibody to an immunogen in the vaccine (Emery '733); and
3) vaccination of birds with SRPs as immunogens (Emery '733).

In addition, the prior art contains the following explicit teachings that are ignored by the Examiner:

1) maternal antibodies to an immunogen have different effects on immunity based on the developmental stage—i.e., *in ovo* compared to post-hatch—of the immune system at the time the maternal antibodies encounter the immunogen;
2) maternal antibodies to an immunogen have a greater likelihood of inducing immune tolerance to the immunogen—exactly the opposite of an adaptive immune response intended as a result of vaccination—when the maternal antibodies encounter the immunogen *in ovo*, even late in the fourth quarter of incubation, as opposed to post-hatch.

"Appellants' assertions are unsubstantiated[.]"

The ability of maternal antibodies to interfere with the development of an adaptive immune response is substantiated, in part, by art cited against Appellants' claims by the Examiner during prosecution. Appellants noted in their response filed May 7, 2009 that Genovese *et al.*, cited by the Examiner in a rejection subsequently withdrawn, acknowledge the difficulty of vaccinating young poults because "the typical humoral/cell-mediated [i.e., adaptive] immune response requires 7 to 10 days to reach protective levels while poultry have been shown to be most susceptible to bacterial species such as Salmonella during the first 4 days of life. In addition, maternal antibodies may cause interference with the vaccine and the desired immune response to that vaccine." (Response, filed May 7, 2009, citing Genovese *et al.*, page 5, emphasis added in Response).

Factors that promote inducing immune tolerance are substantiated in the excerpt from Davis *et al.* eds., *Microbiology*, fourth edition, 1990, J.B. Lippincott Co., Philadelphia,

Pennsylvania, pp. 381-382, entered into the record by citation within the Information Disclosure Statement filed May 7, 2009. Appellants have related the factors, described in general terms in Davis *et al.*, to the specific biological and immunological conditions present *in ovo*. (Appeal Brief, page 16).

The Examiner provides no art-recognized rebuttal to Appellants' positions such as, for example, any publication casting doubt on the Appellants' position regarding what the skilled person would have viewed as the dangers of vaccinating eggs that possess maternal antibodies to an immunogen of the vaccine. Instead, the Examiner relies on her own unsubstantiated "opinion of the Examiner" based on an incomplete understanding of an incomplete selection of the prior art.

The Examiner repeats the assertion that Appellants' remarks are unsubstantiated in, once again, mischaracterizing the claimed subject matter. The Examiner states:

> There is no evidence within the prior art or the Instant [sic] specification which provides indication that *in-ovo* [sic] injection of SRPs in a sustained/delayed matrix would [be] as unpredictable as Appellants assert...[W]hile Appellants argue that the immunological environment of the unhatched embryo is known to those skilled in the art to be sufficiently different from the one-day old [sic] chick...[,] Appellants' claims are not directed toward a newly fertilized egg, but rather, are directed toward egg inoculation in the fourth quarter, substantially before hatching. (Examiner's Answer, page 24).

In making the statement, the Examiner mischaracterizes the scope of the claimed subject in two important ways. First, Appellants' claims are not directed to *in ovo* injection of SRPs in a sustained/delayed release in the manner suggested by the Examiner. Instead, Appellants' claims are directed toward doing so in the specific circumstances in which the egg includes maternal antibodies against an immunogen that is present in the vaccine. Second, the Examiner appears to assert that the influence of maternal antibodies against an immunogen in a vaccine somehow wanes in the fourth quarter of incubation and that the effects on which Appellants' position relies are manifested only in a newly hatched egg. This is factually incorrect. Appellants explained, "Maternally-derived antibodies are stored in the yolk until the

later stages of embryonic development when they are absorbed by the embryonic membranes and transferred to the circulation of the poult to provide passive immunity." (Appeal Brief, page 14, emphasis added). Thus, one skilled in the art appreciates that the threats to generating an adaptive immune response by vaccinating an egg that contains maternal antibodies to an immunogen of the vaccine remains in the fourth quarter of incubation.

The errors highlighted above are repeated throughout the Examiner's Answers in various contexts and reveal a fundamental lack of understanding of avian immunology. For example, the Examiner refers to Emery '733 in which one-day-old poults are vaccinated with a sustained released implant that includes SRPs. The poults possessed maternal antibodies against SRPs and, indeed, declining maternal antibody titers were measured and illustrated in FIG. 3 of Emery '733. The Examiner states:

> Thus, the poults must have had an amount of maternal antibodies that was sufficiently low enough that the poults would be capable of mounting an immune response. Having this knowledge, and taking the suggestion of Emery '479 patent to deliver SRPs *in-ovo* [sic], the ordinary artisan could have predictably created a vaccine to inoculate poultry eggs such as turkey eggs in the fourth quarter of an incubation of an egg to deliver the immunogen[.] (Examiner's Answer, page 18).

The Examiner's conclusion about what the ordinary artisan could have predictably done by combining the teachings of Emery '733 and Emery '479 is incorrect because it ignores that one skilled in the art would have further known that inoculating *in ovo* would increase the likelihood that maternal antibodies to SRPs in the egg could, for example, induce immune tolerance rather than the adaptive immune response demonstrated when the vaccine is administered post-hatch.

As another example, the Examiner characterizes Appellants position incorrectly as follows:

> Further, while Appellants assert that the unpredictability of in-ovo [sic] vaccination arises due to the contention that a sustained release of antigen, [sic] the primary objective of Emery '733 is to provide antigens such as SRP [sic] in a sustained and delayed matrix in order to gradually release SRP as a priming dose...Therefore, the prior art indicates that the sustained release in the presence of maternal antibodies is not deleterious to producing an overall immune

> response and subsequent vaccination. One would thus predict that in-ovo [sic] injection of SRP in a sustained/delayed matrix formulated to deliver SRP at a time when maternal antibodies were sufficiently low so that the bird is capable of mounting an immune response would successfully provide for an immune response (i.e., successful vaccination). (Examiner's Answer, page 19).

This statement again ignores the difference between exposing immunogen to maternal antibodies to the immunogen post-hatch (as taught in Emery '733) and exposing immunogen to maternal antibodies to the immunogen *in ovo*. A person unskilled in the art might make exactly the suggested prediction because an unskilled person would be unaware that in the presence of maternal antibodies against the SRP *in ovo*, an *in ovo* priming dose (a) may fail to prime the unhatched poults' immune system and/or (b) induce immune tolerance for the SRP.

The *in ovo* maternal antibodies against the SRP can bind to the SRP before it encounters any of the poults' immune cells that might be involved in generating the immune response predicted by the unskilled person. The result of the maternal antibodies to SRP binding the *in ovo*-released SRP has two effects, each of which by itself the skilled person appreciates would interfere with the efficacy of the *in ovo* vaccination. First, binding of the SRP by the maternal antibody to the SRP makes the SRP unavailable to the poult's maturing immune cells so that there is no immunological target against which the poult's immune system can mount the adaptive immune response predicted by the unskilled person. Second, binding of the SRP by the maternal antibodies to the SRP can induce immune tolerance in the poult against the immunogen—the poult's immune system is conditioned not to recognize the SRP as a foreign antigen against which an adaptive response should be mounted, but instead erroneously recognizes the SRP as a "self" antigen against which (a) no adaptive immune response is necessary and (b) an adaptive immune response could be deleterious to the poult.

Consequently, a person of ordinary skill in the art would not selectively look at Emery '733 and Emery '479 in a vacuum and to the exclusion of other knowledge regarding the effects of *in ovo* vaccination where the egg contains maternal antibodies against an immunogen of the vaccine. Instead, the skilled person would acknowledge the combined teachings of Emery

'733 and Emery '479 and appreciate that the result of *in ovo* delivery of an immunogen to an egg that possesses maternal antibodies against the immunogen is not predictable from the combination of sustained release vaccination of one-day-old poults with the general acceptability of *in ovo* vaccination with SRPs in the absence of maternal antibodies against SRPs.

The Examiner expands on this incorrect understanding as follows:

> Further, considering *arguendo* that there were a risk [of inducing immune tolerance by vaccinating an egg that contains maternal antibodies to an immunogen in the vaccine], it is the opinion of the Examiner, based upon the success of vaccination of day-old turkey poults with SRPs in a sustained/delayed release matrix in the presence of maternal antibodies, it would have indicated to the ordinary artisan that injection of SRP in-ovo [sic] would have also been successful. (Examiner's Answer, page 26).

As stated immediately above, the skilled person would appreciate that the success of vaccinating poults post-hatch in the presence of maternal antibody against an immunogen in the vaccine fails to predict success vaccinating *in ovo* in the presence of maternal antibody against an immunogen in the vaccine.

The Examiner also asserts that whatever unpredictability exists is not resolved by Appellants' specification. Here, too, the Examiner reveals a basic lack of understating of the scope to which Appellants' claims are drawn. The Examiner points out that Appellants do not state exactly how the biocompatible matrix is prepared, do not measure the maternal antibody titers in the eggs, do not measure antibody titers of the poults after hatching, and do not provide comparative data. (Examiner's Answer, page 21). None of these issues has any impact on the patentability, under 35 U.S.C. §103 or, as hinted at by the Examiner, under 35 U.S.C. §112.

Appellants' claims are not drawn to methods employing particular biocompatible matrices. Moreover, M.P.E.P. §2163(II)(A)(3)(a) states, "The description need only describe in detail that which is new or not conventional. [citations omitted]. This is equally true whether the claimed invention is directed to a product or a process." Biocompatible matrices were well-known in the art and therefore need not be described in detail in Appellants' specification.

Appellants' claims are not drawn to methods in which there is any particular level of maternal antibody present in the egg, any particular antibody titers in the poults after hatching, or any comparative efficacy of the vaccine delivered *in ovo* to eggs that contain maternal antibody to an immunogen in the vaccine. Moreover, Appellants' arguments for the patentability of the claims under 35 U.S.C. §103 do not rely on any particular quantitative result. Instead, Appellants' argument is directed toward the unpredictable nature of the qualitative result—i.e., that one skilled in the art, when considering all of the prior art, would not have been able to predictably induce any adaptive immunity by vaccinating *in ovo* eggs that contain maternal antibody to an immunogen in the vaccine.

The subject matter of Appellants' claims cannot fairly be predicted from the combination of Emery '733 and Emery '479 when these documents are properly considered in the full light of all of the information available to a person skilled in the art at the time the invention was made.

IV. SUMMARY

For the foregoing reasons, Appellant respectfully requests that the Board reverse the rejection of claims 34-44, 67-69, 71-82, and 84-102 as discussed herein and that notification of the allowance of these claims be issued.

Respectfully submitted
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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to Mail Stop - Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17th day of May, 2010.

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CLAIMS APPENDIX

Serial No. 10/749,602

Docket No. 293.00010102

Claims 34-44, 67-69, 71-82 and 84-102 are provided below.

1-33. (Canceled)

34. (Rejected) A method for inducing adaptive immunity in a bird against a selected immunogen comprising:

injecting a biocompatible implant into an egg, wherein the biocompatible implant comprises the selected immunogen and a biocompatible matrix material, wherein the egg comprises maternal antibody to the selected immunogen, wherein the implant provides for sustained release of the immunogen until the maternal antibodies in a bird hatching from the egg are reduced so that the bird is capable of mounting an adaptive immune response to the immunogen, wherein the immunogen comprises a siderophore receptor protein from a gram-negative bacterium.

35. (Rejected) The method according to claim 34, wherein the implant is injected during the fourth quarter of incubation of an egg.

36. (Rejected) The method according to claim 34, wherein the implant is injected at about 15-28 days of incubation of an egg.

37. (Rejected) The method according to claim 34, wherein the bird is selected from the group consisting of turkey, chicken, duck, goose, ostrich and pheasant.

38. (Rejected) The method according to claim 34, wherein the bird is a turkey and the implant is injected at about 25-27 days of incubation of an egg.

39. (Rejected) The method according to claim 34, wherein the implant provides for sustained release of the immunogen for about 1-90 days post-hatching.

40. (Rejected) The method according to claim 34, wherein the implant provides for sustained release of the immunogen for about 1-60 days post-hatching.

41. (Rejected) The method according to claim 34, wherein the implant provides for sustained release of the immunogen for about 1-35 days post-hatching.

42. (Rejected) The method according to claim 34, wherein the implant is injected at about 25-27 days of incubation of an egg and wherein the implant provides for sustained release of the immunogen for about 1-90 days post-hatching of the egg.

43. (Rejected) The method according to claim 34, further comprising administering a second dose of the immunogen at 3-12 weeks post hatching to stimulate a secondary immune response.

44. (Rejected) The method according to claim 34, wherein the bird is a chicken and the implant is injected at about day 17 to 19 of incubation of an egg.

45-66. (Canceled)

67. (Rejected) The method according to claim 34, wherein the implant further provides for delayed release.

68. (Rejected) The method according to claim 34, wherein the immunogen further comprises a porin protein.

69. (Rejected) A method for inducing adaptive immunity in a bird against a selected immunogen comprising:

injecting a biocompatible implant *in ovo*, wherein the biocompatible implant comprises the selected immunogen and a biocompatible matrix material, and hatching eggs to result in birds, wherein the eggs comprise maternal antibody to the immunogen, wherein the implant provides for sustained release of the immunogen until a time when maternal antibodies of the birds to the immunogen are sufficiently reduced so that the birds are capable of mounting an adaptive immune response to the immunogen, wherein the immunogen comprises a siderophore receptor protein from a bacterium.

70. (Canceled)

71. (Rejected) The method according to claim 69, wherein the implant further provides for delayed release.

72. (Rejected) The method according to claim 69, wherein the immunogen further comprises a porin protein.

73. (Rejected) The method according to claim 69, wherein the implant is injected during the fourth quarter of incubation of an egg.

74. (Rejected) The method according to claim 69, wherein the implant is injected at about 15-28 days of incubation of an egg.

75. (Rejected) The method according to claim 69, wherein the bird is selected from the group consisting of turkey, chicken, duck, goose, ostrich and pheasant.

76. (Rejected) The method according to claim 69, wherein the bird is a turkey and the implant is injected at about 25-27 days of incubation of an egg.

77. (Rejected) The method according to claim 69, wherein the implant provides for sustained release of the immunogen for about 1-90 days post-hatching.

78. (Rejected) The method according to claim 69, wherein the implant provides for sustained release of the immunogen for about 1-60 days post-hatching.

79. (Rejected) The method according to claim 69, wherein the implant provides for sustained release of the immunogen for about 1-35 days post-hatching.

80. (Rejected) The method according to claim 69, wherein the implant is injected at about 25-27 days of incubation of an egg and wherein the implant provides for sustained release of the immunogen for about 1-90 days post-hatching of the egg.

81. (Rejected) The method according to claim 69, further comprising administering a second dose of the immunogen at 3-12 weeks post hatching to stimulate a secondary immune response.

82. (Rejected) The method according to claim 69, wherein the bird is a chicken and the implant is injected at about day 17 to 19 of incubation of an egg.

83. (Canceled)

84. (Rejected) A method for inducing adaptive immunity in a population of birds against a selected immunogen comprising:

injecting a biocompatible implant into a population of eggs that comprise maternal antibody to the selected immunogen, wherein the biocompatible implant comprises the selected immunogen and a biocompatible matrix material, wherein the implant provides for sustained release of the immunogen until the maternal antibodies to the immunogen in birds hatching from the eggs are reduced, and the birds hatched from the eggs are capable of mounting an adaptive immune response to the immunogen, wherein the immunogen comprises a siderophore receptor protein from a bacterium.

85. (Rejected) The method according to claim 84, wherein the implant further provides for delayed release.

86. (Rejected) The method according to claim 84, wherein the immunogen further comprises a porin protein.

87. (Rejected) The method according to claim 84, wherein the implant is injected during the fourth quarter of incubation of an egg.

88. (Rejected) The method according to claim 84, wherein the implant is injected at about 15-28 days of incubation of an egg.

89. (Rejected) The method according to claim 84, wherein the bird is selected from the group consisting of turkey, chicken, duck, goose, ostrich and pheasant.

90. (Rejected) The method according to claim 84, wherein the bird is a turkey and the implant is injected at about 25-27 days of incubation of an egg.

91. (Rejected) The method according to claim 84, wherein the implant provides for sustained release of the immunogen for about 1-90 days post-hatching.

92. (Rejected) The method according to claim 84, wherein the implant provides for sustained release of the immunogen for about 1-60 days post-hatching.

93. (Rejected) The method according to claim 84, wherein the implant provides for sustained release of the immunogen for about 1-35 days post-hatching.

94. (Rejected) The method according to claim 84, wherein the implant is injected at about 25-27 days of incubation of an egg and wherein the implant provides for sustained release of the immunogen for about 1-90 days post-hatching of the egg.

95. (Rejected) The method according to claim 84, further comprising administering a second dose of the immunogen at 3-12 weeks post hatching to stimulate a secondary immune response.

96. (Rejected) The method according to claim 84, wherein the bird is a chicken and the implant is injected at about day 17 to 19 of incubation of an egg.

97. (Rejected) The method according to claim 34 wherein the implant further comprises an adjuvant.

98. (Rejected) The method according to claim 69 wherein the implant further comprises an adjuvant.

99. (Rejected) The method according to claim 84 wherein the implant further comprises an adjuvant.

100. (Rejected) The method according to claim 43 wherein the administering a second dose of the immunogen comprises administering a modified live vaccine.

101. (Rejected) The method according to claim 81 wherein the administering a second dose of the immunogen comprises administering a modified live vaccine.

102. (Rejected) The method according to claim 95 wherein the administering a second dose of the immunogen comprises administering a modified live vaccine.